



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,436	07/16/2001	Hermann Wagner	C1041/7010	1340

7590 12/10/2003
Alan W Steele
Wolf Greenfield & Sacks
Federal Reserve Plaza
600 Atlantic Avenue
Boston, MA 02210-2211

EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
----------	--------------

1635

DATE MAILED: 12/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,436

Applicant(s)

WAGNER ET AL.

Examiner

Brian Whiteman

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/24/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-110 and 112-171 is/are pending in the application.
- 4a) Of the above claim(s) 34-103 and 117-171 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 104-110, 112-116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9/24/03 . 6) ☐ Other: _____

DETAILED ACTION

Non-Final Rejection

Claims 34-171 are pending.

Applicants' traversal, the amendment to claim 104, and the cancellation of claim 111 in paper no. filed on 9/24/03 is acknowledged and considered.

Drawings

The drawings were received on 9/24/03. These drawings are not acceptable. New corrected drawings are required in this application because of the objection set forth by the draftsperson. See Form PTO-948. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Election/Restrictions

This application contains claims 34-103 and 117-171 are drawn to an invention nonelected without traverse in Paper No. filed on 1/9/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

Applicants' arguments, see paper no., filed on 9/24/03, with respect to objection to the specification have been fully considered and are persuasive. The objection to the specification has been withdrawn because of the substitute specification submitted by applicants.

Response to Arguments

Applicant's arguments, see paper no., filed on 9/24/03, with respect to 112 first paragraph rejection have been fully considered and are persuasive. The rejection of claims 104-116 has been withdrawn because of the insertion of the word -- vertebrate -- before the word "subject." In addition, the rejection has been withdrawn because applicants display that a poly G sequence in which any four of five consecutive nucleotides is useful for treating a subject having a tumor (see pages 6-8).

Applicant's arguments, see paper no., filed on 9/24/03, with respect to 102(b) rejection have been fully considered and are persuasive. The rejection of claims 104, 105, 107-110, 114 has been withdrawn because of the amendment to the independent claims to incorporate claim 111(see page 9).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1635

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 104, 105, 106, 109, 110, 112, 113, 114, and 115 remain and claims 107 and 108 are rejected under 35 U.S.C. 102(e) as being anticipated by Zupi (US Pat. 6,080,727, EFD 3/26/96). Zupi teaches a method of inhibiting a tumor comprising administering an oligonucleotide (ODN) to a patient, wherein said oligonucleotide is at least 13 bases in length (e.g. SEQ ID NOs: 10 or 17) and has a phosphorothioate linkage (column 36, lines 20-67) and does not comprise a CG dinucleotide. In addition, the method comprises administering an oligonucleotide where the ODN represents the 3' terminus of the ODN (SEQ ID NO: 17) or is RNA (column 5, lines 33-46). Zupi teaches using nucleoside including natural nucleosides and synthetic nucleosides having modified base moieties and/or modified sugar moieties. Such analogs include synthetic nucleosides designed to enhance binding properties (column 3, lines 58-67). The nucleotide sequences (SEQ ID NO: 10 and 17) used in the method taught by Zupi meet the sequence requirement in claim 104 (column 36, claim 32).

Applicants' arguments filed 9/24/03 have been fully considered but they are not persuasive.

With respect to applicants' argument that, "Zupi emphasizes that the G quartet structure alone is not sufficient to inhibit melanoma tumor growth because control oligonucleotides having scrambled sequence and a G quartet were not effective, according to Zupi to inhibit melanoma growth factor (page 8)", the argument is not found persuasive because claim 32 of the patent embraces using SEQ ID NO: 10 and 17 in a method of inhibiting human melanoma. A claim of a US patent is considered enabled. See MPEP 2164. Furthermore, it appears that applicants are contradicting what was taught in the specification by stating that a G quartet is not enabled for treating cancer (human melanoma tumor growth). Clarification is requested.

With respect to applicants' arguments that, "In contrast to Zupi, the instantly claimed invention does not require a sequence specific antisense oligonucleotide complementary to human mRNA to practice the claimed method" and "There is no a priori reason to expect that one skilled in the art would necessarily choose a sequence specific antisense oligonucleotide complementary to human c-myc mRNA that meets all the limitation of the claimed methods (see pages 8-9)," is not found persuasive because as stated above under the 102(e) rejection Zupi anticipates the claimed methods. In addition, Zupi teaches that SEQ ID NO: 10 and 17 can be used to treat human melanoma and thus one skilled in the art would use the SEQ ID NOs to treat human melanoma.

In response to applicant's argument that, "There is no a priori reason to expect that one skilled in the art would necessarily choose a sequence specific antisense oligonucleotide complementary to human c-myc mRNA that meets all the limitation of the claimed methods". The argument is not found persuasive because MPEP § 716.01(c) states:

The arguments of counsel cannot take the place of evidence in the record. In *re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

Furthermore, with respect to applicants' argument that, "the doses useful according to the claimed method are many times smaller than the doses called for in Zupi (see page 9)," is not found persuasive because it is noted that the features upon which applicant relies (i.e., doses useful according to the instant specification, page 12, line 24) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). This is the case here. The claims do not recite the doses taught in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1635

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 104 and 116 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zupi (US Pat. 6,080,727, EFD 3/26/96) taken with Kuby (Immunology, 2nd edition, W.H. Freeman Company, 1994).

Zupi teach a method of treating a tumor in a subject comprising administering an oligonucleotide to the subject, wherein the oligonucleotide does not have a CG dinucleotide (column 36, claim 32). However, Zupi teach using a tumor-specific antigen in combination with said method.

However, at the time the invention was made, tumor-specific antigens were well known in the art for treating a patient with a tumor as evident by Kuby (pages 588-592).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Zupi with Kuby to use a tumor-specific antigen with an oligonucleotide to treat a tumor in a subject. One of ordinary skill in the art would have been motivated to enhance the claimed method by combining the method with a tumor-specific antigen.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments filed 9/24/03 have been fully considered but they are not persuasive because 116 depends on claim 104 the argument is the same as the argument under the 102(e) and was addressed in the response to the argument against the 102(e) rejection.

Furthermore, applicants argue that, "the rejection would not appear to apply to claim 104, which makes no reference to tumor specific antigens (see page 10)." The argument is not found persuasive because it does not pertain to the rejection. Furthermore, claim 116 depends on claim 104 and the limitations of claim 104 are set forth in claim 116.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

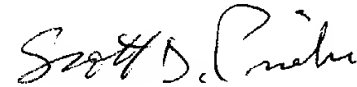
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Art Unit: 1635

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635



SCOTT D. PRIEBE, PH.D.
PRIMARY EXAMINER